

### **REMARKS**

Claims 1, 3, 5-7, 9-15, and 17-26 are currently pending in the application. No claims are presently withdrawn from consideration. Claims 2, 4, 6, 8, and 16 are cancelled. Claims 1, 5, 9, 10-11, 14-15 and 21 are amended. No new matter has been added.

Amendments are to correct informalities in the claims to overcome objections by the Examiner and to cancel matter rejected by the Examiner. Therefore, the amendment can properly be entered after a final rejection. 37 C.F.R §1.116(b) states:

(b) After a final rejection or other final action (§1.113) in an application....:

(1) An amendment may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action;

Entry of the amendment and response after final is respectfully requested.

### **Objections to the Claims**

Applicant thanks the Examiner for the careful reading of the claims. The claims have been amended as set forth above to incorporate language suggested by the Examiner. The amendments require no new consideration by the Examiner.

A. Claim 1 has been amended to remove the redundancy by amending “bacteriophage coat protein polypeptide” to “bacteriophage coat protein” as suggested.

B. Claim 1 has been amended to recite “displayed fusion polypeptide” rather than “displayed polypeptide” as needed.

C. Claim 1 has been amended to correct the informality of the use of the term “phage” rather than “bacteriophage” as suggested.

D, E, and F. Claim 5 has been amended to recite “wherein the plurality of bacteriophage encode a repertoire of polypeptide sequences.” Claim 6 has been cancelled.

G. Claim 9 has been amended to recite “heterologous polypeptide” rather than “heterologous polypeptide or protein” as suggested.

H and I. Claims 10 and 11 have been amended to recite “some displayed fusion polypeptides” instead of some members of the repertoire” as suggested.

J. Claim 14 has been amended to recite “heterologous peptide” instead of “protein or polypeptide” as suggested.

K. Claim 15 has been amended to recite “fusion polypeptides” instead of “proteins” as suggested.

The amendments are purely to correct informalities in the claims and do not alter the scope of the claims. Withdrawal of the objections to the claims is respectfully requested.

#### **Withdrawal of Rejections Under 35 U.S.C. §112, first paragraph**

##### **Written Description**

Applicant thanks the Examiner for the withdrawal of the rejection of claims 1, 3, 5-7, and 9-21 for lack of written description.

##### **Enablement**

Applicant thanks the Examiner for the withdrawal of the rejection of claims 1, 3, 5-7, and 9-21 for lack of written description.

#### **Rejections Under 35 U.S.C. §112, first paragraph**

##### **Enablement**

The Examiner has rejected claim 21 for lack of enablement. The Office Action states that the specification “while being enabling for a method of selection of a bacteriophage comprising exposing the virus to trypsin, thermolysin, subtilisin, Glu-C, or chymotrypsin, the specification

does not reasonably provide enablement for a method of selection of bacteriophage utilizing Factor Xa, Arg-C, or thrombin” (page 6).

Applicant respectfully disagrees. However, purely to progress the prosecution of the instant application, Applicant has cancelled the proteases Factor Xa, Arg-C, or thrombin, overcoming the rejection.

The Office Action alleges that the use of Factor Xa, Arg-C, or thrombin proteases is not enabled by the specification and their use is unpredictable in the method of the invention based on the teachings of Kristensen and Winter, which is discussed at length in the prior response. This is despite the fact that expression vectors containing Factor Xa, Arg-C, or thrombin protease cleavage sites have been long available, strongly suggesting that the proteases work in a predictable manner.

The Office Action points to a comment of the Applicant from the prior response to demonstrate that the characterization of conditions under which Factor Xa, Arg-C, or thrombin would work in the method of the invention would constitute undue experimentation. Specifically, the Examiner points to the statement of the Applicant that “there was no reason to spend the money, time, or resources” to determine cleavage conditions for the other proteases.

In relation to this statement, Applicant would like to clarify that the statement “there was no reason to spend money, time, or resources” characterizing proteases does not suggest that the characterization would constitute undue experimentation. Instead, the experimentation would be unnecessary as there was no need to perform experimentation to arrive at effectively the same endpoint. Having *multiple other proteases that were functional equivalents* to Factor Xa, Arg-C, or thrombin, there was no reason to determine conditions under which Factor Xa, Arg-C, or thrombin would cleave. In the methods in the Kristensen and Winter reference, there was *no specific advantage to using one protease over the other*. Having accomplished the desired selection using the protease cleavage step, “there was no reason to spend the money, time, or resources” to undertake the academic exercise of determining cleavage conditions for other proteases.

Applicant reserves the right to pursue a continuation application to obtain claims to the cancelled matter.

**Rejections Under 35 U.S.C. §112, first paragraph**

The Examiner has rejected claims 1, 3, 5-7, 9-15, and 17-26 for being indefinite and failing to particularly point out and distinctly claim the subject matter.

Applicant has amended claim 1 to recite “the displayed fusion” polypeptide, overcoming the rejection. The amendment does not alter the scope of the claim.

Based on the amended claims and arguments presented above, Applicant submits that one of skill in the art would be fully enabled to perform the invention commensurate in scope with the claims. Applicant respectfully requests withdrawal of the rejection.

**CONCLUSION**

In view of the above amendments and remarks, Applicant believes the pending application is in condition for immediate allowance. If the Examiner believes that there are any outstanding issues remaining in the case, the Examiner is strongly encouraged to call the Agent for Applicant listed below. Any additional fee occasioned by this paper may be charged, or overpayment credited to, Deposit Account 04-1105, Reference No. 208039/1090.

Respectfully submitted,

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